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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,185	08/27/2001	Kevin Gunderson	A-69605-1/DJB/RMS/DCF	3512

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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,185

Applicant(s)

GUNDERSON ET AL.

Examiner

Juliet C. Switzer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election without traverse of group I, claims 1-13 in the paper filed 1/27/03 is acknowledged. Non-elected claims 14-16 were cancelled. In response to a further restriction requirement, a group of one hundred capture probes, namely SEQ ID NOs: 18-40, 42-54, 56-113 and 117-122, was elected for prosecution. For all examined claims, this group was considered. Prior to allowance, the non-elected sequences will be required to be deleted from the claims.

2. Applicant is advised that should claim 1 be found allowable, claims 7 and 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Applicant is advised that should claim 9 be found allowable, claims 10 and 11 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It is noted that in the instant case the claims, as written have different limitations (i.e. "at least 25 different addresses," "at least 50 different addresses," and "at least 100 different addresses"), however, in light of applicant's election of a single set of 100 nucleic acid probes for examination, the elected invention for each of these claims is a set of 100 different probes, and thus the claims are substantial duplicates of one another. The same is true for claims 9-11.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s): Specifically, there is no compact disc copy of the sequence listing as

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required by 1.821(c) and 1.152(e)(4). In a paper filed 1/31/02, applicant submitted a single compact disk containing a computer readable form of the sequence listing (see applicant's remarks in noted paper). This computer readable form was forwarded to the STIC and entered into the USPTO's computer system. The amendments to the specification filed with this paper incorporate by reference a compact disk in place of the paper copy of the sequence listing. In order for this application to be in compliance with the sequence rules TWO copies of the CD that is meant to be the paper copy of the sequence listing must be submitted.

Rule 1.152(e)(4) states, in part, "Any compact disc must be submitted in duplicate unless it contains only the "Sequence Listing" in computer readable form required by § 1.821(e)...." In the instant case, the paper copy of the sequence listing required by 1.821(c) must be submitted in duplicate, in addition to the computer readable form of the sequence listing that was previously submitted.

In order to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), Applicant must submit a paper copy of the Sequence Listing (or two copies of the appropriate compact disks) containing these sequences as well as all appropriate amendments and statements as required by 37 CFR 1.821 - 1.825 and 37 CFR 1.152.

4. Preliminary amendments to the specification filed 1/31/02, 1/27/03, and 2/20/03 have been entered.

Claim Objections

5. Claims 1-13 are objected to because of the following informalities: They refer to tables in the claims. MPEP 2173(s) states "Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table is permitted only in exceptional

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circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." In the instant case, sequences in the tables can each be referred to by proper sequence identifier, and thus the referral to tables in the claims is not practically necessary. Appropriate correction is required.

6. Claims 6 is objected to because it recites "said wherein" bridging lines 1 and 2 of the claim, and this language does not make grammatical sense. Correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-4 are indefinite over the recitation "wherein said capture probes are microspheres" because it is unclear how a capture probe can be a nucleic acid selected from one of the tables (as required by claim 1) and also a microsphere at the same time. Clarification is required, for example to indicate that the nucleic acid capture probes are attached to microspheres.

In claim 5, the phrase "said solid support" in lines 1-2 lacks proper antecedent basis because the claim does not previously recite a solid support.

In claim 13 the phrase "said nucleic acid sequence" lacks proper antecedent basis because it is unclear which of the nucleic acid sequences recited in claim 9 is meant to be "said nucleic acid sequence."

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The elected invention is drawn to nucleic acid arrays and sets of nucleic acids that comprise 100 specific nucleic acid sequences as identified by SEQ ID NOs: 18-40, 42-54, 56-113 and 117-122. The specification asserts that these arrays and nucleic acids are useful as a type of "universal array" such that complements of the members of the array are ligated onto target samples and then hybridized to the array. The specification does not provide any reasoning or asserted utility that is specific to the elected set of nucleic acids, but instead generically asserts a utility which is generally applicable to an entire class of molecules, that is to any randomly selected nucleic acid sequence. Indeed, the prior art (for example Balch *et al.* 6083763) teaches generically the utility of universal arrays (see Col. 16-20), but again fails to give specific utility for the instantly claimed invention. Applicant's invention, while drawn to the use of particular nucleic acid sequences fails to disclose any specific use for the collection claimed. Thus, the claimed invention is not supported by a specific asserted utility that relates to the particular subject matter claimed. This is precisely like the situation in the utility guidelines, where "a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or

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"chromosome marker" would not be considered specific in the absence of a disclosure of a specific DNA target (see page 5 of Utility guidelines)." Here, the array is simply a nucleic acid array for capture, but there are no specific DNA targets contemplated. The selection of the particular DNA sequences was an arbitrary selection from a pool of a hundreds of trillions of trillions of different possible sequences. Therefore, there is no specific utility for the claimed arrays.

Claim 1-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by 1997

Biochemicals Catalog, Boehringer Mannheim, p. 95.

The Biochemicals Catalog provides a kit comprising a hexanucleotide mix that comprises a mixture of hexamer nucleotides of all possible sequences. This hexanucleotide mix inherently comprises nucleic acids that are substantially complementary to the sequences of the elected set, and in fact are entirely complementary to portions of each of the elected nucleic acids. The specification sets forth that "substantially complementary" sequences are sufficiently

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complementary to target sequence to hybridize under some selected reaction conditions. The mixture provided in the biochemicals catalog meets this requirement of the claims. Furthermore, the mixture provided in the biochemicals contains at least a first universal priming sequence since it is specifically suited for random-priming of nucleic acids, and it comprises a sequence complementary to a target domain since it contains every possible 6-mer and some of these are inherently complementary to some target domain. Amendment of the claims to recite the particular probes as listed by SEQ ID NO or their complements would overcome this rejection.

Conclusion


13. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Juliet C Switzer
Examiner
Art Unit 1634

June 13, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER